

LISTING OF THE CLAIMS

As no claims amendments are submitted with this paper, this listing of the claims is provided solely for the Examiner's convenience. Within this listing of the claims, claims 1-26 are pending.

1. **(Original)** A method for selecting an optimized controlled release dosage form for administration to a patient such that the dosage form will have a predetermined drug release profile *in vivo*, the method comprising:
 - (a) preparing a plurality of different candidate dosage forms each comprised of a biocompatible, hydrophilic polymer and a pharmacologically active agent incorporated therein;
 - (b) obtaining the *in vitro* drug release profile for each candidate dosage form in an aqueous medium in a USP disintegration tester;
 - (c) comparing the *in vitro* drug release profiles obtained in (b), and determining which of the *in vitro* drug release profiles correlates most closely with a desired *in vivo* drug release profile; and
 - (d) selecting the dosage form having the determined *in vitro* drug release profile for administration to a patient.
2. **(Original)** The method of claim 1, wherein the candidate dosage forms are all comprised of the same biocompatible, hydrophilic polymer but differ with respect to the amount or molecular weight thereof.
3. **(Original)** The method of claim 1, wherein the candidate dosage forms all contain the same pharmacologically active agent but differ with respect to the amount thereof.
4. **(Original)** The method of claim 1, wherein the biocompatible, hydrophilic polymer is selected from the group of cellulosic polymers, polyalkylene oxides, naturally occurring hydrophilic polymers, crosslinked polyacrylic acids, and mixtures thereof.
5. **(Original)** The method of claim 4, wherein the biocompatible, hydrophilic polymer is a cellulosic polymer.
6. **(Original)** The method of claim 5, wherein the cellulosic polymer is selected from the group consisting of methylcellulose, hydroxymethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, carboxymethylcellulose, and mixtures thereof.

7. **(Original)** The method of claim 4, wherein the biocompatible, hydrophilic polymer is a polyalkylene oxide.

8. **(Original)** The method of claim 7, wherein the polyalkylene oxide is selected from the group consisting of poly(ethylene oxide), polyethylene glycol, poly(ethylene oxide)-polypropylene oxide copolymers, and mixtures thereof.

9. **(Original)** The method of claim 8, wherein the polyalkylene oxide is poly(ethylene oxide).

10. **(Original)** The method of claim 4, wherein the biocompatible, hydrophilic polymer is a naturally occurring hydrophilic polymer.

11. **(Original)** The method of claim 10, wherein the naturally occurring hydrophilic polymer is selected from the group consisting of collagen, fibronectin, albumins, globulins, fibrinogen, fibrin, thrombin, aminated polysaccharides, guar gum, xanthan gum, carageenan, alginates, pectin, activated polysaccharides, and mixtures thereof.

12. **(Original)** The method of claim 1, wherein the active agent is insoluble or sparingly soluble.

13. **(Original)** The method of claim 1, wherein the active agent is soluble.

14. **(Original)** The method of claim 13, wherein drug particles of the active agent are encased in protective vesicles.

15. **(Original)** The method of claim 14, wherein the protective vesicles are liposomes.

16. **(Original)** The method of claim 15, wherein drug particles of the active agent are coated with an enteric coating.

17. **(Original)** A method for delivering a pharmacologically active agent to the upper gastrointestinal tract of a patient over an extended period of time while minimizing delivery to the lower gastrointestinal tract and colon, the method comprising orally administering to a patient in whom the fed mode has been induced a sustained release oral dosage form comprised of a therapeutically effective

amount of the pharmacologically active agent incorporated in a matrix of at least one biocompatible, hydrophilic polymer that:

(a) swells in the presence of water in gastric fluid such that the size of the dosage form is sufficiently increased to provide gastric retention of the dosage form in the stomach of a patient in whom the fed mode has been induced;

(b) gradually erodes within the gastrointestinal tract over a determinable time period; and

(c) releases the active agent throughout the determinable time period,

wherein the dosage form is optimized by subjecting the dosage form to a disintegration test for an extended period of time such that the dosage form has an *in vitro* active agent release profile that correlates to a desired *in vivo* active agent release profile for the dosage form.

18. **(Original)** The method of claim 17, wherein the dosage form erodes at a rate that is faster than the rate at which the dosage form swells.

19. **(Original)** The method of claim 17, wherein at least 40% of the active agent is retained within the matrix one hour after ingestion of the dosage form.

20. **(Original)** The method of claim 19, wherein 60 to 80 % of the active agent remains in the matrix one hour after ingestion.

21. **(Original)** The method of claim 20, wherein at least 85% of the active agent is released from the matrix within six to eight hours after ingestion.

22. **(Original)** The method of claim 17, wherein the active agent is an anti-microbial agents.

23. **(Original)** The method of claim 22, wherein the anti-microbial agent is ciprofloxacin.

24. **(Original)** The method of claim 17, wherein the active agent is calcium carbonate.

25. **(Original)** The method of claim 17, wherein the active agent is one of an ACE inhibitor, an angiotensin II antagonist, or a beta-adrenergic blocking agent in combination with a diuretic.

26. **(Original)** The method of claim 17, wherein the dosage form is administered once daily.